



**SUNRISE
MEDICAL**

DEC 15 2000

K001491

Sunrise Home Healthcare Group
Mobility Products Division
7477 A East Dry Creek Parkway
Longmont, CO 80503
Tel: (303) 218-4500
Fax: (303) 218-4590

510(k) SUMMARY

Submitter's Name and Address

Sunrise Medical
7477 East Dry Creek Parkway
Longmont, Colorado 80503
Phone (303) 218-4500
Fax (303) 218-4793

Contact Person: Bryan Dannettell, Manager of QA/RA

Date Prepared: May 9, 2000

Device Trade or Proprietary Name

Sunrise Medical Model Quickie 2 Power Assist Wheelchair

Device Common or Usual of Classification Name

Wheelchair, Powered

Identification of predicate device

Sunrise Medical Model P90(P120) Power Wheelchair (k972230)

Description of the device

Quickie 2 Power Assist Wheelchair is a light duty, conventional, rear wheel drive, folding wheelchair. The wheelchair is a combination of a standard Quickie 2 manual wheelchair (re:K850536) that incorporates a power assist component supplied by Yamaha Motor Corporation, USA. As a motorized wheelchair, it contains motors, drive wheels and batteries.

The wheelchair is propelled using a mix of human power to manually turn the chair wheels which activates the power assist electric motors to provide a short burst of supplementary power.

Intended use

Quickie powered wheelchairs empower physically challenged persons by providing a means of enhanced mobility.

Comparison of device characteristics to predicate

This device (Sunrise Medical Model Quickie 2 Power Assist Wheelchair) has similar technological characteristics as the predicated device (Sunrise Medical Model P90(120) Power Wheelchair). The device and predicate device are folding wheelchairs. They use steel and aluminum in their frame and components, and standard material and covers for the slings and backs. Microprocessors are used. Motors employ direct electrical current with rechargeable batteries for an energy source. The operating speeds and maneuverability are equivalent, and recommended for indoor or light outdoor use. Standard accessories and components are common.

The device uses a mix of human and electrical power to propel the wheelchair, whereas the predicate device uses all electrical power to propel the wheelchair.

Non-Clinical Testing

This device has been tested to both ISO7176 and ANSI/RESNA Wheelchair Standards. They include:

ISO 7176-1, ANSI/RESNA W/C 1	Maximum Overall Dimensions
ISO 7176-1, ANSI/RESNA W/C 1	Determination of Static Stability
ISO 7176-2, ANSI/RESNA W/C 2	Determination of Dynamic Stability of Electric Wheelchairs
ISO 7176-3, ANSI/RESNA W/C 3	Determination of Effectiveness of Brakes
ISO 7176-4, ANSI/RESNA W/C 4	Determination of Energy Consumption of Electric Wheelchairs
ISO 7176-5, ANSI/RESNA W/C 5	Determination of Overall Dimensions, Mass and Turning Space
ISO 7176-6, ANSI/RESNA W/C 6	Determination of Maximum Speed Acceleration and Retardation
ISO 7176-7, ANSI/RESNA W/C 7	Method of Measurement of Seating and Wheel Dimensions
ISO 7176-8, ANSI/RESNA W/C 8	Static Impact and Fatigue Strength Test
ISO 7176-9, ANSI/RESNA W/C 9	Climatic Test for Electric Wheelchairs
ISO 7176-10, ANSI/RESNA W/C 10	Determination of Obstacle Climbing Ability of Electric Wheelchairs
ISO 7176-14, ANSI/RESNA W/C 14	Testing of Power and Control System for Electric Wheelchairs
ISO 7176-21, ANSI/RESNA W/C 21	Requirements and Test Methods for Electromagnetic Compatibility

Conclusion

Analysis of comparison of design, function and features of the Sunrise Medical Model Quickie 2 Power Assist Wheelchair to the Sunrise Medical Model P90(120) Power Wheelchair together with the results of compliance testing to existing ANSI/RESNA standards for powered wheelchairs demonstrates the device to be substantially equivalent to the predicate in terms of meeting performance criteria and functioning as intended.

The Quickie Power Assist Wheelchair is substantially equivalent to the predicated device listed in this 510(k) and does not raise any issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Mr. Bryan Dannettell
Manager, Quality and Regulatory Affairs
Sunrise Medical, Inc.
7477 East Dry Creek Parkway
Longmont, Colorado 80503

Re: K001491

Trade Name: Quickie 2 Power Assist Wheelchair
Regulatory Class: II
Product Code: ITI
Dated: October 3, 2000
Received: October 4, 2000

Dear Mr. Dannettell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

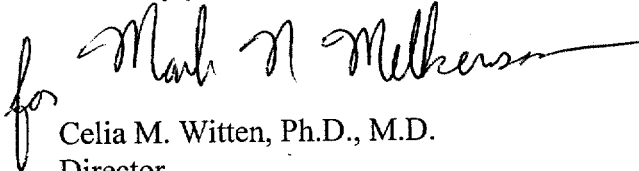
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 -- Mr. Bryan Dannettell

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

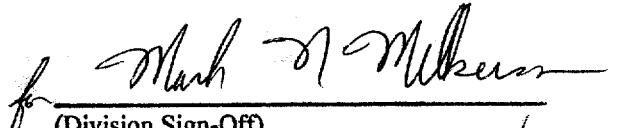
Indications for Use

Quickie powered wheelchairs empower physically challenged persons by providing a means of mobility.

510(k) number: Not assigned as of this time

Device name: Quickie 2 Power Assist Wheelchair

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001491

Prescription use (per 21 CFR801.109)

Over-the-counter use